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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,058	06/30/2006	Yair Saar	0146.00002	5559

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,058	SAAR, YAIR	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *12-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/28/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-11, 29-36 in the reply filed on 12/19/2007 is acknowledged.

Claims 12-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/19/2007.

Claim Rejections - 35 USC § 112

Claims 1-5, 11, 29-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the integrated viral complex" in regard to claim . There is insufficient antecedent basis for this limitation in the claim.

Claim 36 is confusing; is "via injection or from 1 day of age" really meant as alternatives?

Claims 1-5, 11, and 29-36 involve the term "integrated viral complex". The specification does have an explicit definition of this term on page 6, lines 14-16, as meaning "live virions contained, or cocooned, in host cell membranes with a reduced cytosolic content." However, the term is not consistently used according to this explicit definition; for example, in claim 1, the term is defined differently as "comprising (a) a plurality of intact cell membranes, each of said intact membranes belonging to a non-viable cell; and (b) a plurality of viable virions, a majority of said virions of said plurality

of viable virions contained within said intact cell membrane belonging to said plurality of intact cell membranes." These are different in scope: the page 6 definition, for example, encompasses live host cells, and the claim 1 definition encompasses materials with normal cytosolic content. Therefore, after reading and understanding the specification, it is unclear what defines the metes and bounds of "an integrated viral complex."

Claims 1-11, 29-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-11 require "a plurality of intact cell membranes, each of said membranes belonging to a non-viable cell." The specification provides no information on how to exclude all viable cells from the claimed composition of matter. On page 14, the specification teaches to passage virus cultures at 75% CPE, but does not provide any guidance on how to eliminate all viable cells during or after harvest. Methods of inactivating virus compositions are well known in the vaccine art, and these methods would render cells nonviable, but would also render virions nonviable. Therefore, considering the scope of the claims, the absence of teachings in the specification, and the absence of working examples for the method as claimed, it is concluded that undue experimentation would be required to make the invention as claimed.

Claims 1-11 and 29-36 all require "an integrated viral complex" or at least viable virions inside intact cell membranes of nonviable cells. The claims are broad in scope,

drawn to all viruses, DNA viruses, double-stranded DNA viruses, herpes viruses, most specifically Marek's disease virus. The specification briefly describes a method of preparing viruses that involves mixing or suspending infected cells in a cryprotectant, (e.g. the paragraph spanning pages 7-8) but it is not clear how this method relates to the claimed product. Figure 1 also outlines process steps, but it is again unclear how this process relates to the claimed product. A working example is presented on specification pages 14-15, but it is confusing on many points. It states that "virus was propagated when 75% or more of the monolayer was cytopathically affected", but it is not clear if this sentence relates to the roller bottle cultures in the preceding sentence, or if it refers to the previous scale-up passages. It is also is unclear what was harvested or when was "the end of the incubation period". The instructions regarding addition of medium A are impossible – if 10% v/v of “medium M199 with glycerol 50%” is added to the resuspended cells, then the suspension has 5% glycerol; if another 10% is added 15 minutes later then the suspension has 10% glycerol; there is no way to follow the teachings of the example to achieve the full range of 2-8% glycerol. Page 15 says to add Solution B, “a sterile stabilizer,” but does not indicate the composition of Solution B. The next paragraph discloses a stabilizer recipe, but it is not clear if that is the same or different from “solution B.” Considering the broad scope of the claims, the limited teachings in the specification, the lack of clarity regarding what is actually contained in the claimed product, and the confusing working example, it is concluded that undue experimentation would be required to make the claimed products and use them in the claimed vaccination process.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1-11, 29-34, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spijkers et al, US 5789231. Spijkers teaches growing Marek's disease virus in roller bottle cultures to high titers, harvesting the infected cell layers by trypsinzation, concentrating the cells by centrifugation, diluting the cells in freezing medium, and filling vials for frozen storage. See Example 1. This appears to be very similar to the process followed in the instant working example. Spijkers also teaches vaccination of chickens with the product, see example 2. Spijkers does not state that the freezing medium contains a cryoprotectant. However, Spijkers explicitly suggests freezing cells and cell-associated virus in the presence of cryoprotectors, such as DMSO or glycerol, see column 3 lines 48-50. Therefore it would have been obvious to use a cryoprotector in the freezing medium. Considering the similarity between the processes followed by reference example and the instant working example, and considering the obvious variation of using cryoprotectant in the freezing medium, following the process suggested by the reference would result in a product with the same characteristics as applicant's "integrated viral complex". Therefore, the claimed product is seen as prima facie obvious, absent unexpected results, and the process of using it is also seen as prima facie obvious.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spijkers et al 5789231 as applied to claims 1-11, 29-34, 36 above, and further in view of Yokogawa et al EP 1064947. Claim 35 differs from Spijkers in requiring vaccination *in ovo*. However, Yokogawa teaches vaccination of chickens in ovo with attenuated Marek's disease virus, including cell-associated virus, see the Abstract. Yokogawa teaches appropriate attenuated strains include strain CVI-988 strain virus (used also in Spijkers) and host cells QT-35 (used also in Spijkers). Therefore, it would have been within the ordinary skill of the art to modify Spijkers by vaccinating in ovo for the advantages taught in Yokogawa, with reasonable expectation of success. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

3/10/08